

## Steps for Registering Your Non-Cancer Center Trial on ClinicalTrials.gov

USC Principal Investigators (PIs) are responsible for determining whether or not they are obligated to register and for any subsequent required updates including results reporting, in accordance with U.S. Public Law 110-85, Title VIII (or FDAAA) and/or other applicable requirements.

- [Click here for details on \*Why Register?\*](#)
- [Click here for information on \*Who is Responsible for Registering the Trial on Clinicaltrials.gov?\*](#)

## Steps for Registering Your Non-Cancer Center Trial on ClinicalTrials.gov

1. To request User account set up to the **Clinicaltrials.gov Protocol Registration System** (PRS) to register your trial, contact the appropriate **USC PRS Administrator** below:

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| <p><b>For Non-Cancer Center Trials contact:</b></p> <ul style="list-style-type: none"><li>▪ Jean Chan, Associate Director HSC<br/>Dept. of Contracts and Grants<br/>Phone: (213) 821-7134 or<br/>Email: <a href="mailto:jeanbcha@usc.edu">jeanbcha@usc.edu</a></li></ul> | <p><b>For Cancer Center Trials contact:</b></p> <p>The <a href="#">Clinical Investigations Support Office (CISO)</a> of the <b>USC Norris Comprehensive Cancer Center</b> (for Cancer Center faculty with clinical trials) <b>to receive separate instructions for registering cancer center trials:</b></p> <ul style="list-style-type: none"><li>▪ Victoria Soto<br/>Phone: (323) 865-0432 or Email: <a href="mailto:Victoria.soto@med.usc.edu">Victoria.soto@med.usc.edu</a></li></ul> |
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- Include **Clinicaltrials.gov** in the *subject line* if request is via email
  - Provide your full name/USC phone #/USC email address, and
  - Provide the USC Lead PI's full name/USC phone #/USC email address, if you are not the PI.
2. After receiving an auto-email from Clinicaltrials.gov with user login name and a temporary password, login to the **Clinicaltrials.gov PRS** at <https://register.clinicaltrials.gov/> and complete the login fields:
    - In the "Organization" field, enter USC's organization name as "USCalifornia" (no spaces/case sensitive).
    - Follow the instructions to change your temporary password to one you will remember.
  3. Go to **Main Menu > Protocol Records > Create**, then follow the prompts for creating your registration and filling in a series of data entry screens. Click on the various fields to access instructions for that field.
    - **Please note:** Under the **Responsible Party** field:
      - *The Responsible Party should always be the Principal Investigator.*
    - **Important Reminder:** *As the PI or designee, you are responsible for entering your trial information, ensuring that it is correct, and updating the registry in a timely manner as required by law.*
    - **Tip:** Information may be copied and pasted into the data fields from an electric version of your protocol.
  4. Once all required sections/screens have been completed, the *Edit Protocol* screen will appear. Review the information provided and ensure all errors, comments, etc., have been addressed before clicking "**Complete**", in the top, left corner of the screen.
  5. The "Responsible Party" (USC PI), can then "**Approve**" & "**Release**" the record to Clinicaltrials.gov.
  6. Following a successful Clinicaltrials.gov system validation and internal QA review, the record will be *Posted* and made available to the public through the Clinicaltrials.gov website within 2-5 business days of release. New records may take up to 10 business days to be assigned an **NCT number** and appear in the databank.

**Keep your Protocol Record Updated:** A verification or update of the data in active protocol records is required every six (6) months. Failure to login to the PRS and confirm or update your record(s) every six (6) months, regardless of whether there has been a change or not, may result in loss of funding and/or inability to publish the results of a study in an ICMJE associated journal. **(Note:** Upon login to the PRS, ensure the "**Record Verification Date**" field is changed to reflect the current date.)

- **Important Tip:** *Clinicaltrials.gov will send a reminder email notification to you to update your study once every six (6) months.*

**Questions?** If you have questions about registering a trial at ClinicalTrials.gov, contact the appropriate **USC PRS Administrator** or **Clinicaltrials.gov** at [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov).